EXHIBIT B

Department of Health and Human Services
OFFICE OF MEDICARE HEARINGS AND APPEALS
Cleveland Field Office
Cleveland, Ohio

Appeal of:	**D. Christenson**	ALJ Appeal No.:	**1-8285652321**
Beneficiary:	**D. Christenson**	**Medicare Part B**	
HICN:	*******3639A**	Before:	**Thomas S. Tyler** U.S. Administrative Law Judge

DECISION

After carefully considering the evidence and arguments presented in the record, a **FULLY FAVORABLE** on-the-record decision is entered for the Beneficiary.

Procedural History

Novocure, Inc., the provider, submitted claims to Medicare for tumor treatment field therapy (TTFT), electric stimulation cancer treatment (E0766) it provided to the Beneficiary from January 3, 2018 to April 3, 2018. The claims were denied initially and upon reconsideration. The matter was then forwarded to C2C Solutions, Inc., a qualified independent contractor (QIC), which issued an unfavorable decision on December 27, 2018 and found the provider liable for payment of the non-covered services.

The Office of Medicare Hearings and Appeals (OMHA) received the Appellant's timely filed appeal. The remaining amount in controversy meets the jurisdictional requirements for a hearing before OMHA.

A telephone hearing in this matter was scheduled to be held on March 28, 2019 at 1:30 PM EST in Cleveland, Ohio before the undersigned ALJ. However, because all of the issues have been resolved in the Beneficiary's favor, a hearing was not conducted and a decision on-the-record has been entered pursuant to 42 C.FR. §405.1000(g). All exhibits were entered into the record as evidence.

Issue

The issue is whether the tumor treatment field therapy (TTFT) provided to the Beneficiary from January 3, 2018 to April 3, 2018 is covered under Medicare Part B.

Findings of Fact

The Beneficiary in this case is a 65 year-old man who was diagnosed with glioblastoma (GBM) in July 2015. Specifically, he had a right occipital brain tumor. He had surgery and was treated with chemotherapy and radiation. Thereafter, his physician prescribed the tumor treatment field therapy (TTFT). The TTFT is durable medical equipment that delivers alternating electric fields or tumor treating fields to the brain. The device consists of an electric field generator which is connected to four insulated transducer arrays. The arrays are placed on the patients scalp and deliver the tumor treating fields therapy in order to interfere with the growth of the patient's glioblastoma tumors. (Exhibit 2; Beneficiary's Pre-hearing Brief).

The physician signed a renewal prescription form for Optune on November 29, 2017. (Exhibit 2, p. 56). NOVO-TTF transducers were delivered to the Beneficiary on January 3, 2018, February 3, 2018, March 3, 2018 and April 3, 2018. (*Id. at pp. 52-55*).

The record contains multiple articles regarding the efficacy of the use of Optune for the treatment of both initially discovered and recurring glioblastoma. (Exhibit 1). The following historic information is identified in the documentation:

In April 2011, the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) approved commercial distribution of the Optune device for treatment of adult patients (22 years of age and older) with histologically-confirmed glioblastoma multiforme (GBM) following histologically- or radiologically- confirmed recurrence in the supratentorial region of the brain after receiving chemotherapy. In the pre-market approval letter, CDRH noted the device was intended to be used as a monotherapy, and was intended as an alternative to standard medical therapy for GBM after surgical and radiation options had been exhausted.

In October 2015, the CDRH issued a pre-market approval supplement for Optune. The supplement approved Optune as a treatment for adult patients (22 years of age or older) with histologically-confirmed GBM and Optune with temozolomide for the treatment of adult patients with newly diagnosed, supranentorial glioblastoma following maximal debulking surgery and completion of radiation therapy together with concomitant chemotherapy.

In 2018, the National Comprehensive Cancer Network (NCCN) Guidelines (version 1.2018; March 20, 2018) were updated to include alternating electric field therapy (TTFT) as an NCCN category I recommendation following post-operative standard brain radiation therapy with concurrent temozolomide. (See CD, file "NCCN_CNS_2018.pdf"). (Exhibit 3).

Peer-reviewed literature suggests that tumor-treating fields, also known as alternating electric fields, disrupt the cell division process in cancerous tumors which may lead to programmed cell death, or apoptosis. Tumor treating fields have shown statistically significant improvement in patient survival and outcomes in GBM brain tumors compared with traditional standards of care alone. (Exh. 2, pp. 49-79; *See* also, CD, Optune Peer Reviewed Literature; *Hearing Record*).

A large number of health care insurance providers have medical policies in place allowing coverage for Optune for the treatment of glioblastoma multiforme when certain conditions are met. These providers include, but are not limited to AETNA, Highmark, Anthem, Humana, Kaiser, United Healthcare, Cigna, Geisinger, and Blue Cross Blue Shield. (*See* CD, Optune Medical Policies November 2018; *Hearing Record*).

Legal Framework

I. ALJ Review Authority

A. Jurisdiction

An individual who, or an organization that, is dissatisfied with the reconsideration of an initial determination is entitled to a hearing before the Secretary of the Department of Health and Human Services (HHS), provided there is a sufficient amount in controversy and a request for hearing is filed in a timely manner. Social Security Act (Act) § 1869(b)(1)(A).

In implementing this statutory directive, the Secretary has delegated the authority to administer the nationwide hearings and appeals system for the Medicare program to OMHA. *See* 70 Fed. Reg. 36386, 36387 (June 23, 2005). The ALJs within OMHA issue the final decisions of the Secretary, except for decisions reviewed by the Medicare Appeals Council. *Id.*

A hearing before an ALJ is only available if the remaining amount in controversy is $160 or more. *See* 76 Fed. Reg. 59138 (Sept. 23, 2011) and 42 C.F.R. §405.1006(b)(2). The request for hearing is timely if filed within sixty days from the date the party receives notice of the QIC's reconsideration. *See* 42 C.F.R. § 405.1014(b)(1).

B. Scope of Review

Under the implementation policy of the Centers for Medicare and Medicaid Services, United States Department of Health and Human Services, all appeal requests stemming from a QIC reconsideration are governed by the Administrative Law Judge Hearing Procedures outlined in 42 C.F.R. §§ 405.1000 – 1018. 70 Fed. Reg. 11425 (March 8, 2005).

The issues before the administrative law judge include all the issues brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in the party's favor. However, if evidence presented before the hearing causes the administrative law judge to question a favorable portion of the determination, the administrative law judge will notify the parties before the hearing and may consider it an issue at the hearing. 42 C.F.R. § 405.1032(a).

C. Standard of Review

The Office of Medicare Hearings and Appeals is staffed with Administrative Law Judges who conduct de novo hearings. 42 C.F.R. § 405.1000(d).

II. Principles of Law

A. Statutes and Regulations

The Medicare program, Title XVIII of the Social Security Act (the Act), is administered through the Centers for Medicare and Medicaid Services (CMS), a component of the United States Department of Health and Human Services (HHS). Under the authority of Section 1842(a) (1) (A) of the Act, the Secretary of HHS is authorized to enter into contracts with private entities for the day-to-day operations of the program.

Part B of Title XVIII, the Supplementary Medical Insurance program, provides coverage for a variety of medical services and supplies furnished by physicians, or by others in connection with physicians' services, for outpatient hospital services, and for a number of other specific health-related items and services. Individuals participate voluntarily in the Medicare Part B program and pay a monthly premium.

Sections 1832(a)(2)(B), 1861(s)6), and 1862(a)(1)(A) of the Act provide that Part B covers durable medical equipment (DME) that is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII, § 1833(e) of the Act provides that no payment shall be made to any provider of services or other person under this part unless there has been furnished such information as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.

B. Medicare Manual System

Administrative Law Judges may also give consideration to the manuals and rulings issued by the CMS in determining benefit coverage and eligibility. Although not binding on the Administrative Law Judge, the respective manuals provide guidance in the administration of the Medicare program. (*Shalala v. Guernsey Memorial Hospital*, 514 U.S. 87 (1995)).

Section 1871(a)(2) of the Act provides that no rule, requirement or statement of policy, other than a National Coverage Determination ("NCD"), can establish or change a substantive legal standard governing the scope of benefits or payment for services under the Medicare program unless it is promulgated as a regulation by CMS. However, although not subject to the force and effect of the law, CMS and its contractors, have issued policy and guidelines, including Local Coverage Determinations (LCD's) that describe criteria for coverage for selected types of medical services and supplies. NCDs promulgated by the Secretary of HHS under the authority of § 1862(a)(1) of the Act dictate the criteria under which specified services, procedures or supplies are covered by Medicare. NCDs are binding upon ALJs. 42 CFR §405.732(a)(4). "An ALJ may not disregard, set aside or otherwise review an NCD." (42 CFR §405.732(b)(1)).

There is no NCD specific to tumor treatment field therapy. However, there is a local coverage determination that can be found at L34823. Local Coverage Determination, L34823 addresses tumor treatment field therapy (TTFT). It states:

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

Tumor treatment field therapy (E0766) will be denied as not reasonable and necessary.

A4555 ELECTRODE/TRANSDUCER FOR USE WITH ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, REPLACEMENT ONLY

E0766 ELECTRICAL STIMULATION DEVICE USED FOR CANCER TREATMENT, INCLUDES ALL ACCESSORIES, ANY TYPE

Policy article A52711 that supplements the LCD provides that "Tumor treatment field therapy devices are covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met."

Further, the Policy Article States that "Code E0766 is in the frequent and substantial service payment category. Items included in this payment category are reimbursed a single monthly fee schedule amount for the device and all related supplies and accessories. Separate billing of supplies and/or accessories will be denied as unbundling."

Analysis

At issue in this case is whether reimbursement can be made for the TTFT therapy provided to the Beneficiary in four monthly applications from January 3, 2018 to April 3, 2018.

The Local Coverage Determination that addresses TTField therapy, L34823, specifically denies coverage. It states that tumor treatment field therapy (E0766) will be denied as not reasonable and

necessary. The LCD does not provide any circumstances under which TTField therapy would be covered.

The Beneficiary in this case has glioblastoma and was given a prescription by his treating physician to use TTField therapy following resection, radiation and chemotherapy. The Beneficiary, through his counsel, stated that he understands that there is an LCD that states that TTField therapy is not medically reasonable and necessary but notes that the last revision of the LCD L34832 was in 2013. The Beneficiary explained that the Optune therapy system that is at issue in this case was FDA approved for treatment of glioblastoma in 2015.

While we acknowledge that Medicare appropriately considered LCD L34832 in making the decision to deny the TTField therapy in this case based upon the unambiguous pronouncement that "tumor treatment field therapy (E0766) will be denied as not reasonable and necessary," we decline to follow that statement in the LCD. The Code of Federal Regulations identify the applicability of Local Coverage Determinations. It states that LCDs are required to be adhered to by Medicare contractors. (42 C.F.R. §405.1062). However, Administrative Law Judges and the Medicare Appeals Council are not bound by LCDs. If an ALJ declines to follow an LCD in a particular case, he or she may do so, but must explain why the policy was not followed. (*Id.*).

LCD L34832 does specifically state that TTField therapy will be denied as not reasonable and necessary. The tumor treatment field therapy that the Appellant is seeking is called "Optune." "Optune is a portable battery or power supply operated device which produces alternating electrical fields, called tumor treatment fields (TTFields) within the human body. The TTFields are applied to the patient's shaved head by means of electrically insulated surface transducer arrays, such that resistively coupled electric currents are not delivered to the patient. The TTFields disrupt the rapid cell division exhibited by cancer cells." https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf. The peer-reviewed literature shows that tumor treating fields disrupt the cell division process in cancerous tumors which may lead to programmed cell death. Tumor treating fields have also shown statistically significant improvement in patient survival rates and outcomes in GBM brain tumors when compared with the traditional standard of care alone. While we acknowledge that the QIC appropriately considered LCD L34823 in making the decision to deny the Optune treatment in this case based upon the unambiguous pronouncement that the type of treatment is not reasonable and necessary, we feel we must decline to follow that statement in the LCD. No explanation was provided by the LCD for the failure to cover the TTField therapy. Certainly, the LCD is not required to include reasons for the denial of non-covered services. However, in giving an LCD its required deference when considering whether to abide by a pronouncement that is not binding on an ALJ, the reason for the non-coverage would be helpful to assess the applicability of the LCD. Here, we cannot determine the reasons for non-coverage but find that the rationales for finding coverage are extensive. In exercising our review authority, we hereby provide the bases for why we decline to follow the pronouncement in the LCD. (42 C.F.R. §405.1062(a)).

Without an explanation in the LCD as to why TTF therapy is considered as not medically reasonable and necessary, we are left to speculate. The TTFT was likely an emerging technology that had not been widely reviewed or tested for medical efficacy at the time the language was included in the LCD limiting its coverage. However, Optune was approved by the FDA for use in

the treatment of newly diagnosed glioblastoma on October 5, 2015[1]. Moreover, at around the same time of the last LCD update, there were studies conducted and the results published passing on the efficacy of the use of TTField therapy, most notably the Optune (NovoTTF-100A therapy), for recurrent and new diagnoses of glioblastoma. *Stupp et al., NovoTTF-100A versus physician's choice chemotherapy in recurrent glioblastoma: a randomized phase III trial of a novel treatment modality*. Eur J Cancer. 2012 Sep; 48(14):2192-202. The results of further studies were presented in the Annual Meeting of the American Association for Cancer Research. *Stupp, Hegi, Ibdaih, et al. Tumor treating fields added to standard chemotherapy in newly diagnosed gliobastoma (GBM): final results of a randomized, multicenter phase III trial*, Program and Abstracts of the 2017 Annual Meeting of the American Association for Cancer Research April 1-April 5, 2017 Washington, D.C. Abstract LBA AACR CT007. The results of these studies determined that Optune in combination with temozolomide was an effective treatment of this particular brain cancer, whether newly diagnosed or recurrent, that resulted in significant improvement in life expectancy of most patients.

We are also persuaded by the Beneficiary's medical provider. The Beneficiary's physician prescribed the treatment at issue in this case based upon the numerous studies and articles that described the medical effectiveness of Optune and based upon his own experience with the treatment.

On the basis of the foregoing, we decline to follow the LCD. The FDA approval of Optune, the overwhelming medical research evidence and the medical notes of the Beneficiary's physician discloses that Optune is effective in extending the lives of patients who have been newly diagnosed or have recurrent glioblastoma. We do not fault Medicare contractors for coming to a different conclusion. They adhered to the pronouncement in the LCD. However, if ever there was a reason for an ALJ to vary from the strict, unexplained pronouncement in an LCD, it is this case where the very life of the Beneficiary holds in the balance, with very few, if any, other medical options to treat him and prolong his life aside from the treatment provided by the Optune device.

Consequently, the undersigned finds that the Medicare requirements have been met. Accordingly, the ALJ finds that the TTFT treatment provided to the Beneficiary in this case are covered under Medicare Part B.

Conclusions of Law

Based on the foregoing, the undersigned concludes as a matter of law that the Optune Tumor Treatment Field Therapy services were shown to be medically reasonable and necessary and are covered under Medicare. The Beneficiary is entitled to reimbursement of the costs billed.

[1] https://www.accessdata.fda.gov/cdrh_docs/pdf10/P100034S013b.pdf

Order

The Medicare Contractor is **DIRECTED** to process the claim in accordance with this decision.

SO ORDERED.

Dated: 4/2/19

Thomas S. Tyler
U.S. Administrative Law Judge